(19)

No. 98-1768

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF MEDTRONIC SOFAMOR DANEK, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

JAMES M. BECK
Counsel of Record
MICHELLE HART YEARY
PEPPER HAMILTON LLP
3000 Two Logan Square
Philadelphia, PA 19103-2799
(215) 981-4000

STEPHEN S. PHILLIPS
Special Counsel for
MEDTRONIC SOFAMOR DANEK, INC.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-2695

Counsel for Amicus Curiae

September 13, 2000

BURRUPS PACKARD® / APPELLATE DIVISION, 1617 JFK BOULEVARD, PHILA., PA 19103 (215) 563-8000

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INTEREST OF THE *AMICUS CURIAE*

Medtronic Sofamor Danek, Inc. ("MSD"), is successor in interest to Sofamor Danek Group, Inc. ("SDG"), parent of the largest suppliers of the spinal implants at issue in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, from which this appeal arises.[1] SDG brought the initial motion to dismiss claims of fraud committed against the Food and Drug Administration ("FDA"), *see* MDL 1014 Docket No. ("MDL Dkt. #") 5103. The Court of Appeals held that SDG was not entitled to status as an appellant, *see* Appendix accompanying Petition for *Certiorari* ("Pet. App.") at 8a n.3, but SDG participated as *amicus curiae* in the Court of Appeals, *id.*, and in support of the petition for *certiorari* in this Court.

MSD should be permitted to participate as *amicus curiae* before this Court because its subsidiaries are suppliers of orthopædic bone screws, and thus are targets of the full range of "fraud on the FDA" claims in this litigation. Accordingly, MSD has relevant information concerning the broader impact of "fraud on the FDA" claims, both in this litigation and upon FDA administrative determinations generally.

MSD's participation as *amicus curiae* will assist the Court in understanding the profound impact of allowing common-law reexamination of the bases of FDA decisions — and by extension, of any federal administrative action — in private tort actions under state law.

SUMMARY OF ARGUMENT

Respondent Plaintiffs' Legal Committee ("PLC") represents hundreds of plaintiffs in personal injury litigation against suppliers of orthopædic bone screws used during plaintiffs' spinal fusion surgeries. "Fraud on the FDA" is one of the PLC's many state-law claims. The PLC asserts that virtually every important FDA decision concerning these screws since

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1. No counsel for any party authored any portion of this *amicus curiae* brief, and no one other than MSD made any monetary contribution to the preparation or submission of this brief. Supreme Court Rule 37.6.

1985 rests upon untrue information provided by the suppliers of these devices or their agents. This "fraud," the PLC claims, allows state-law juries to treat these FDA regulatory actions as if they did not exist, and to hold defendants liable for supplying products lacking any FDA marketing permission.

Without the Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§301, *et seq.*, there could be no claim that FDA was defrauded — because no FDA submission requirements would exist. Thus "fraud on the FDA" claims violate the FDCA's prohibition against private rights of action. 21 U.S.C. §337(a). Either under the express preemption provision of the Medical Device Amendments ("MDA") to the FDCA, 21 U.S.C. §360k(a), or under principles of implied preemption, claims of "fraud on the FDA" are preempted.

Without preemption, state-law juries could reexamine almost everything FDA does and could reach different conclusions regarding the validity of FDA actions. Refusal of state tort law to recognize an in-force federal administrative decision inherently conflicts with that federal decision and, more broadly, with the supremacy of federal law.

The pervasive interference with FDA actions that "fraud-on-the-FDA" claims entail is exemplified by the breadth of the PLC's charges against MSD here. The disruptive effect of such claims upon FDA administration of federal law is very real — as the course of this litigation likewise demonstrates.

ARGUMENT

In enacting the MDA in 1976, Congress sought to protect public health by balancing the need to regulate medical devices with the need for development of new and improved devices without excessive cost or delay.[2] A critical part of that

2. *See* S. Rep. No. 33, at 7 (1976) ("a balance [should] be struck between the need for continuing research and the need for improved patient protection"), at 13 (intent that "innovation is not stifled" and that " 'quack' devices or devices known to be unsafe or ineffective" not be allowed) (reprinted at 1976 U.S.C.C.A.N. 1074, 1075, 1076, 1083); H.R. Rep. No. 853, 94th Cong., 2d Sess. at 10 (1976) ("protection against unsafe, unproven,

balance — preservation of FDA's ability to do its job without being second-guessed in state tort litigation — is threatened by the claims before the Court on this appeal.

I. "Fraud On The FDA" Claims Expose FDA Decisions To Collateral Attack In State Courts, In Direct And Inherent Conflict With The Regulatory Scheme Enacted By Congress.

A. The PLC's Claims Seeking Nullification Of Almost Every FDA Decision Regulating Spinal Implants Between 1985 and 1998 Have Been Repeatedly Reviewed By FDA.

The PLC has brought "fraud on the FDA" claims against FDA decisions concerning every maker of orthopædic bone screws. *See* Pet. App. at 43a-44a; *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, 1996 WL 482977, at *2 (E.D. Pa. Aug. 22, 1996) (PTO 477). These claims controvert the validity of scores of FDA clearances of spinal implant devices since 1984, including FDA's 1995 decision to begin clearing "pedicle screws" as such and FDA's general reclassification of "pedicle screw spinal systems" proposed in 1995 and finalized in 1998. *See* 63 Fed. Reg. 40025 (FDA Jul. 27, 1998); 60 Fed. Reg. 51946 (FDA Oct. 4, 1995).[3] Repeatedly, the PLC has brought its extravagant charges to FDA's attention, but the Agency has rejected those claims, both explicitly and implicitly.

The *John Lee Ramey* complaint, the MDL Court's exemplar of claims against MSD's subsidiary, Danek Medical, Inc. ("Danek")[4] (reproduced in pertinent part as Appendix "A") reveals the ambitious scope of the PLC's "fraud on the FDA"

ineffective and experimental medical devices" is "counterbalanced by an equally strong conviction that excessive . . . regulation would stifle progress").

3. FDA's Final Rule was published on July 27, 1998, after oral argument in the court below. FDA decisions published in the Federal Register are entitled to judicial notice. 44 U.S.C. §1507.

4. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1997 WL 186325, at *2 n.3 (E.D. Pa. Apr. 16, 1997) (PTO 861), *aff'd*, 193 F.3d 784 (3d Cir. 1999).

claims. It alleges that the initial 1986 FDA clearance of Danek "Luque II" components, used in surgery seven years later in 1993, was fraudulent because Danek supposedly misstated the "intended use"[5] of its screw components. App. "A" at 3a ¶¶90-100. There is no claim that Mr. Ramey, his surgeon, or anyone involved in his treatment knew of or acted in detrimental reliance upon any misstatement. *Id.* at 8a ¶¶126-28.

The *Ramey* complaint further alleges that Danek defrauded FDA with respect to devices not even used in Mr. Ramey's surgery. These allegations likewise involve "intended use," rather than the physical characteristics, medical risks, or medical benefits of any device:

- In 1988-89 and 1990-92, Danek allegedly misstated the "intended use" of various screw components of a device called the "TSRH" system. *Id.* at 6a-7a ¶¶105-15.
- In 1991-92, Danek allegedly misstated the "intended use" of the screw components of a device called the "Dyna-Lok" system. *Id.* at 7a-8a ¶¶120-25.

Other fraud allegations involve FDA's January 20, 1995 decision to clear TSRH screws labeled for use in the pedicles of the lumbar spine. Although this event occurred after Mr. Ramey's 1993 surgery, the *Ramey* complaint alleges that Danek (aided by other screw suppliers) submitted a false affidavit to FDA.[6] App. "A" at 13a-18a ¶¶244-75.

Still more fraud allegations in the *Ramey* complaint involve FDA's October 4, 1995 proposal to reclassify "pedicle screw spinal systems" to make future clearances easier to obtain. The PLC attacks a large "cohort study" that FDA concluded was "valid scientific evidence" of the safety and

5. "Intended use" is an FDA term of art. "Intended uses" described in a manufacturer's proposed labeling will be cleared only if FDA considers them substantially equivalent to intended uses of the predicate or preamendment device upon which the manufacturer's application for marketing and labeling clearance is based. *See* 21 C.F.R. §801.4.

6. All device clearances in the *Orthopedic Bone Screw* litigation involve the same "substantial equivalence" or "§510(k)" procedure discussed in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478-480 (1996).

effectiveness of bone screws when used for pedicle fixation. *Id.* at 9a-13a ¶¶240-43. *See* 60 Fed. Reg. at 51947, 51950-54.[7]

The PLC's "fraud on the FDA" allegations are not limited to one device, one supplier, or one incident. Each of hundreds of state-law cases attacks FDA decisions to allow marketing of most spinal fixation screws that now exist and to void regulatory steps FDA has taken since 1995 to address the administrative status of these devices. The PLC's "fraud on the FDA" claims are nothing less than an attempt to use state law to nullify over ten years of FDA regulatory activity. By these claims, the PLC seeks to have juries re-examine each of these FDA clearances, find them to be the product of fraud, and hold manufacturers liable as if no FDA clearance had ever been granted.

The history of the PLC's "fraud on the FDA" allegations demonstrates how second-guessing FDA decisions is the essence of such claims. FDA has examined the identical fraud allegations and found them wanting. FDA's proposal to reclassify spinal implants invited public comments, and the MDL Court allowed the PLC to use MDL discovery to make comments.[8] The PLC's public comments filed with FDA are 231 pages long and have 402 exhibits.[9] The PLC Comments asserted the same fraud charges made in this litigation against petitioner Buckman, AcroMed Corp. (which hired Buckman), Danek, and many others:

- "[D]evice manufacturers applied for §510(k) clearance to market the devices for pretextual uses." PLC Comments at 32; *see generally id.* at 33-37.

7. Reclassification is a separate process by which FDA can issue a lower device classification if presented with "valid scientific evidence" of a device's safety and effectiveness. 21 U.S.C. §360c(e); 21 C.F.R. §§860.7, 860.120-860.134.

8. *See* 60 Fed. Reg. at 51946 (calling for public comments); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1995 WL 764580, at *5 (E.D. Pa. Dec. 14, 1995) (PTO 179) (PLC may use confidential MDL documents in its public comments to FDA).

9. *See* "Comments by Plaintiffs' Legal Committee in *In re Orthopedic Bone Screw Products Liability Litigation*, MDL Docket 1014, Concerning Proposed Rule Making," FDA Dkt. No. 95N-0176 (filed March 1, 1996) ("PLC Comments").

- "[R]epresentations which AcroMed made to FDA concerning the intended use of its bone plates and bone screws were plainly false and misleading." *Id.* at 37; *see generally id.* at 34-39.
- The "1995 510k clearance . . . represents an unwarranted and unprecedented departure from the agency's prior position which violates the agency's own regulations and which occurred under suspicious circumstances." *Id.* at 215; *see generally id.* at 211-15.
- "[T]he Cohort Study . . . and, ultimately, the proposal of the downclassification regulation itself were the result of clandestine deals between certain employees of the FDA and industry." *Id.* at 90; *see generally id.* at 90-175.

In its July 27, 1998 Final Rule approving reclassification, FDA addressed the PLC's fraud claims. It refused to prohibit bone screws due to "deception":

> After reviewing all available data and information, . . . FDA does not believe that pedicle screw spinal systems present a substantial deception or an unreasonable and substantial risk of illness or injury. Consequently, FDA does not believe it would be appropriate to ban them.

63 Fed. Reg. at 40035-36 (Item 28). FDA further determined that prior screw clearances were not fraudulent or misleading and should be retained.[10] FDA reviewed the PLC's fraud allegations concerning the cohort study in great detail and rejected the PLC's claims point by point. *Id.* at 40029-30 (Items 2-3).

The PLC then filed a citizen's petition with FDA under 10 C.F.R. §10.30, seeking revocation of the January, 1995 TSRH §510(k) clearance, an investigation into supposed false, fraudulent or misleading Danek submissions, and/or a referral

10. *Id.* at 40030 (Item 3) (no corruption of data by financial relationships between surgeons and manufacturers); at 40031 (Item 8) (retaining prior Class II designation); 40032-33 (Items 13-16) (rejecting attack upon January, 1995 clearance and claims of corrupt "deal"); 40039 (Item 44) (retaining most prior labeling; allowing abbreviated resubmissions for devices previously cleared for pedicle use).

for criminal prosecution. MDL Dkt. #6732, Exhibit 1. The PLC's citizen petition rehashes the same "fraud on the FDA" claims:

- "Danek . . . and others agreed to obtain fraudulent and false documents and testimony . . . and submit such evidence to the FDA." *Id.* at 18.
- "Danek vigorously massaged the . . . affidavit to deliberately mislead the FDA." *Id.* at 23.
- "Based on the false, fraudulent or misleading information submitted by Danek . . . the FDA's determination of 'substantial equivalency' of the TSRH pedicle screw must be revoked." *Id.* at 25-26.

The PLC was again permitted to use confidential MDL discovery material in support of its citizen's petition.[11] FDA undertook another investigation of these allegations, but took no steps against Danek.[12]

In addition, hundreds of PLC plaintiffs filed complaints under the Federal Tort Claims Act ("FTCA"), 28 U.S.C. §§2671, *et. seq.*, alleging FDA negligence in granting the same clearances to market orthopædic bone screws. MDL Dkt. #6440, Exhibit F at ¶17 (exemplar complaint). The PLC's FTCA claims likewise claimed "fraud on the FDA" by reason of misstated "intended use." *Id.* at ¶¶14-17. The MDL court dismissed these FTCA claims. It found a "discretionary function" in order "to prevent judicial 'second-guessing' of legislative policymaking."[13]

Further, the PLC has a pending lawsuit against FDA under the Administrative Procedures Act, 5 U.S.C. §§551, *et. seq.* (1988) ("APA"). *See In re Orthopedic Bone Screw Prod-*

11. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. Jul. 30, 1998) (PTO 1537); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. May 21, 1998) (PTO 1448).

12. FDA's Status Report, filed in *Cosom, et al. v. United States Food & Drug Administration*, C.A. No. 98-4643, Dkt. #18 (E.D. Pa., filed Aug. 2, 1999) (related case docket to MDL 1014).

13. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1998 WL 964498, at *3 (E.D. Pa. Nov. 3, 1998). The PLC abandoned its appeal from that dismissal.

ucts Liability Litigation, MDL 1014, 1999 WL 455667 (E.D. Pa. Jul. 2, 1999) (PTO 1813) (PLC has standing to pursue APA claim). Once again, the PLC made its familiar attacks upon the cohort study and claimed that manufacturers "fraudulently sought and received FDA permission to market [bone screws] . . . for pretextual 'intended' uses." PLC APA complaint ¶¶69, 161-69.[14]

An additional measure of the PLC's effort to second-guess FDA is what it sought to put before this Court. **Everything** the PLC designated for the Joint Appendix (except complaints, declarations and judicial opinions) was in the exhibits to the PLC Comments submitted to FDA, and some **72 percent** of AcroMed/Buckman related exhibits submitted to FDA (54 of 75 AcroMed exhibits) were designated by the PLC here.[15]

Notwithstanding the numerous occasions upon which the PLC brought its "fraud on the FDA" allegations to FDA's attention — and FDA's access to all MDL discovery since January 5, 1996[16] — FDA first pursued and then finalized its October, 1995 proposal to reclassify the devices at issue in this litigation. 63 Fed. Reg. 40025 (FDA Jul. 27, 1998). Nor has FDA ever withdrawn or challenged the validity of any bone screw manufacturer's §510(k) clearances.

The PLC's "fraud on the FDA" allegations in the *Orthopedic Bone Screw* litigation, and FDA's adverse determination of them, expose the error of the lower court's reasoning. The PLC's attempt to overturn FDA clearances of every device in this litigation shows that its "fraud on the FDA" claims would impose a legal requirement — not to sell devices that FDA has cleared to be marketed — "different from or in addition

14. Amended Complaint, filed in *Cosom, et al. v. United States Food & Drug Administration*, C.A. No. 98-4643, Dkt. #5 (E.D. Pa., filed Dec. 7, 1998) (related case docket to MDL 1014).

15. The PLC's July 20, 2000 designation letter demanded that the Joint Appendix include Exhibits 1-37, 42-53, 65-67, 208 and 215 to the PLC Comments to FDA.

16. *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1996 WL 901283 (E.D. Pa. Jan. 5, 1996) (PTO 192) (granting FDA access to MDL discovery).

to" FDA requirements under the FDCA. *See* 21 U.S.C. §360k(a). "Fraud on the FDA" claims are not just "different." They are incompatible with the FDA actions they attack, and are therefore preempted.

Just as starkly, these claims illuminate how "fraud on the FDA" claims inherently conflict with the same FDA actions they seek to nullify, and are thus impliedly preempted. *See Medtronic, Inc. v. Lohr,* 518 U.S. 470, 503 (1996) (recognizing conflict preemption under MDA) (plurality opinion), 507-08 (same) (Breyer, J. concurring); *McDermott v. Wisconsin,* 228 U.S. 115, 132-34 (1913) (applying conflict preemption under FDCA). Aside from the court below, every Court of Appeals presented with a state-law tort claim alleging fraud supposedly committed against a federal agency has found preemption because such claims "conflict" with, "second guess" or "collaterally attack" federal administrative determinations. *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997), *cert. dismissed,* 523 U.S. 1113 (1998); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir.), *cert. denied*, 523 U.S. 1020 (1998); *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 306-07 (5th Cir.) (identical claims), *cert. denied*, 515 U.S. 1104 (1995); *Papas v. Upjohn Co.*, 985 F.2d 516, 518-19 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993). The course of this litigation — the PLC's repetitive attacks upon FDA's regulation of these products — establishes that the majority of courts are correct, and that the court below is mistaken.

"Fraud on the FDA" claims are preempted because they are inherently collateral state-law attacks upon in-force federal regulatory decisions. States, however, must accept supreme federal law. It is a "truism that States may not preempt federal law." *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990).[17] "Common law" may not be invoked to set aside federally issued approvals, arrived at after extensive review, because plaintiffs "disagree with the regulatory approach taken by the agency." *City of Milwaukee v. Illinois*, 451 U.S.

17. Superceded by statute as stated in *Deck v. Peter Romein's Sons*, 109 F.3d 383, 388 (7th Cir. 1997).

304, 323 (1981). Tort claims that "actually conflict[]" with federal law cannot stand. *Geier v. American Honda Motor Co.*, 120 S. Ct. 1913, 1922 (2000). The PLC may not, in these state-law cases, ask lay juries to reexamine and set aside FDA decisions that allow these medical devices to enter the nationwide market.

B. The Regulatory Structure Enacted By Congress Precludes The PLC's Attempted Collateral Attack Upon FDA Decisions.

The potential for state-law "fraud on the FDA" claims to disrupt FDA's administration of the FDCA is also apparent from the Agency's role in the statutory scheme. The FDCA does not invest FDA with authority to seek out and investigate drugs or medical devices for possible clearance. *Benton v. Kessler*, 799 F. Supp. 281, 284-85 (E.D.N.Y.), *mot. denied*, 506 U.S. 1084 (1992); *see* S. Rep. No. 468, at 204, 101st Cong., 2d Sess. (1990) (no FDA authority to establish clinical research facilities). Nor does FDA have authority to evaluate "off-label"[18] uses on its own volition. 21 U.S.C. §360c(i)(1)(E)(i-ii); S. Rep. No. 284, at 76, 104th Cong., 2d Sess. (1996). Like many administrative bodies, FDA acts in response to information that the governing statute requires regulated persons, and allows others, to submit to the Agency.

Requirements for submission of information to FDA are pervasive. The three avenues by which medical devices come onto the market each require evaluation of information submitted by manufacturers, distributors, and their agents.[19] So

18. Physicians may prescribe medical devices and drugs as they see fit, regardless of FDA-labeled indications. 21 U.S.C. §396. Such off-label use "is commonplace in modern medical practice and ubiquitous in certain specialties." *Washington Legal Foundation v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000) (citations omitted). FDA has not regulated teaching of off-label uses, *id.* at 335; 65 Fed. Reg. 14286, 14287 (FDA Mar. 16, 2000), thus PLC attacks upon purported "promotion" of off-label use at medical seminars are without legal basis.

19. *See* 21 U.S.C. §360e(c); 21 C.F.R. §814.20 (describing information to be submitted to FDA in support of pre-market approval application); 21 U.S.C. §360c(e-f); 21 C.F.R. §860.123 (same; reclassification); 21 U.S.C. §§360(k), 360e(b); 21 C.F.R. §§807.87-807.93 (same; pre-market notification).

do approval processes for new drugs and biologics.[20] After FDA has given permission for a product to be marketed, manufacturers and distributors must provide a wide variety of additional information to FDA, any of which could lead to future FDA action.[21] Every action based upon submitted information is potentially subject to second-guessing and common-law nullification if "fraud on the FDA" claims survive preemption.

Nor does FDA need common-law assistance because it cannot defend itself from an onslaught of false information. Quite the contrary, the FDCA provides FDA with an imposing arsenal of sanctions should the Agency conclude that it has been the victim of fraud. In addition to felony criminal sanctions under 18 U.S.C. §1001, FDA has numerous administrative sanctions at its disposal:

- injunctions against violations or further marketing, 21 U.S.C. §332;

20. *See* 21 U.S.C. §355(a-d,i); 21 C.F.R. §§312.20-23, 314.50-54 (submission requirements for new drugs); 42 U.S.C. §262 (a,j); 21 C.F.R. §§601.3, 601.20-601.25 (submission requirements for new biologics).

21. **Devices:** *E.g.*, 21 U.S.C. §§360i (record keeping), 360j(f)(2) (variance from good marketing practices), 360l (post-market surveillance); 360ll, 360nn (a-b,d,f) (electronic inspection/reporting), 360aaa-3 (supplemental application for new use); 21 C.F.R. §§803.1-.56, 804.1-.35 (adverse experience), 806.10, 820.100 (corrections), 807.20-.31 (device/establishment listing), 810.10(d), 810.15-.16 (cease distribution/ recall), 820.30 (design/development), 820.70(b) (production/process changes), 820.120 (labeling), 820.181-.186, 821.50 (records), 820.198 (complaints), 821.20-.25 (device tracking), 860.7, 860.120-860.134 (reclassification). **Drugs:** *E.g.*, 21 U.S.C. §§355(k) (record keeping), 356b (postmarketing study), 356c (discontinuation), 360 (registration/listing), 360b(e)(1)(F) (failure to supplement application); 21 C.F.R. §§201.1-.15, 201.50-.57, 201.60-.63, 211.134(d,e), 314.70 (labeling), 207.20-.37 (establishment/drug listing), 211.180-.196 (record keeping), 211.198 (complaints), 310.303, 314.81, 314.420 (records/reports), 314.54 (indication changes), 314.70-.71 (supplement to approved application), 314.72 (change of ownership), 314.80 (adverse experience). **Biologics:** *E.g.*, 21 C.F.R. §§600.12 (record keeping), 600.14 (errors), 600.21-.22 (inspections), 600.80 (adverse experience), 600.81 (distribution), 601.4 (licenses), 601.12 (changes to approved applications), 601.26 (reclassification), 610.9, 610.11(c) (procedure modifications), 610.60-.64 (labeling).

- enhanced criminal penalties upon proof of "intent to defraud," *id.* §333(a);
- civil fines to $1,000,000, *id.* §§333(b)(2)(B), 333(f)(1)(A), 335b(a);
- seizure and forfeiture, *id.* §334(a)(2)(D);
- detention without prior notice, *id.* §334(g);
- barring implicated companies or individuals from involvement with further submissions to FDA, *id.* §335a(a-e);
- denial, suspension, or termination of activities tainted by fraud, *id.* §335a(f-h);
- withdrawal of approval, *id.* §335c;
- warning letters for "minor violation[s]," *id.* §336;
- permanent ban of the product at issue, *id.* §360f; and
- mandatory recall. *Id.* §360h(e).

Nor has FDA been reluctant to use its powers. Recent case law abounds with prosecutions of false statements to FDA.[22] Many FDA enforcement actions are for false or fraudulent submissions. For example, from March 1993 through January 2000, FDA permanently debarred 48 persons and temporarily debarred 2 others for providing false information.[23] FDA has also disqualified 87 clinical investigators from participation in clinical trials and has restricted numerous others.[24]

State-law "fraud on the FDA" claims thus are not needed to assist FDA enforcement efforts. Rather, such claims com-

22. *E.g., United States v. Sigma International, Inc.*, 196 F.3d 1314 (11th Cir. 1999); *United States v. Bhutani*, 175 F.3d 572 (7th Cir. 1999), *cert. denied*, 120 S. Ct. 1173 (2000); *United States v. Haas*, 171 F.3d 259 (5th Cir. 1999); *Takhar v. Kessler*, 76 F.3d 995 (9th Cir. 1996); *United States v. Ballistrea*, 101 F.3d 827 (2d Cir. 1996); *DiCola v. FDA*, 77 F.3d 504 (D.C. Cir. 1996); *United States v. Chatterji*, 46 F.3d 1336 (4th Cir. 1995).

23. *See FDA, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy — Debarment List* (last modified Jun. 20, 2000) <http://www.fda.gov/ora/compliance_ref/debar/default.htm>.

24. *See FDA Disqualified/Restricted Assurances List for Clinical Investigators* (last modified Jun. 13, 2000) <http://www.fda.gov/ora/compliance_ref/bimo/dis_ref_assur.htm>.

plicate FDA administration of the statute by pursuing matters FDA does not wish pursued. The FDCA gives complete prosecutorial discretion to FDA:

> Nothing in this chapter shall be construed as requiring the [FDA] to report for prosecution . . . minor violations of this chapter. . . .

21 U.S.C. §336. "The Act's enforcement provisions . . . commit complete discretion to [FDA] to decide how and when they should be exercised." *Heckler v. Chaney*, 470 U.S. 821, 835 (1985). As discussed, *supra*, at p. 6, FDA spent more than two years investigating the PLC's "fraud on the FDA" claims before rejecting them in issuing its 1998 Final Rule.

C. Allowing Tort Claims That Cannot Exist Apart From The FDCA Violates The Statute's Prohibition Of Private Rights Of Action.

In direct contrast to FDA's multi-faceted enforcement capabilities, the FDCA provides no enforcement role for would-be "private attorneys general" such as the PLC. The FDCA provides:

> Except as provided in subsection (b) of this section [relating to actions by state governments], all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §337(a). Thus, this Court in *Medtronic*, 518 U.S. at 477 (plurality opinion), and every Court of Appeals to consider the question, have held that no private rights of action exist under the FDCA.[25] In §337(a), the FDCA "expressly restricts its enforcement to the federal government." *In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 784, 791 (3d Cir. 1999).

25. *E.g., Cottrell, Ltd. v. Biotrol International, Inc.*, 191 F.3d 1248, 1254-55 (10th Cir. 1999); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997); *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), *cert. denied*, 510 U.S. 1197 (1994); *Rodriguez v. SK&F Co.*, 833 F.2d 8, 9 (1st Cir. 1987); *Fiedler v. Clark*, 714 F.2d 77, 79 (9th Cir. 1983); *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367, 370 (7th Cir. 1976).

"Fraud on the FDA" claims are not ordinary product liability tort claims. They do not challenge any aspect of the product in question except its manufacturer's dealings with FDA. Without the FDCA and the submission procedures it mandates, there could be no claim for "fraud on the FDA." Attacks focused upon the regulatory pedigree of a medical device or drug correspond to no common-law tort. *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 159-61 (4th Cir. 1999).

A supposed state-law claim incapable of existing apart from a federal statute is a *sub rosa* attempt to create a private right of action under the statute by operation of state law. This Court addressed the interplay of the FDCA and state law in a related context in *Merrell-Dow Pharmaceuticals Inc. v. Thompson*, 478 U.S. 804 (1986). In considering whether FDCA-related tort allegations gave rise to federal subject matter jurisdiction, the Court "assumed" (because neither party disputed) that Congress did not intend to allow private FDCA rights of action. 478 U.S. at 811. The Court noted that to allow FDCA violations as the sole basis for an ostensibly state-law cause of action conferring federal jurisdiction would "flout" this "assumed" Congressional intent:

> The significance of the necessary assumption that there is no federal private cause of action thus cannot be overstated. For the ultimate import of such a conclusion . . . is that it would flout congressional intent to provide a private federal remedy for the violation of the federal statute. We think that it would similarly flout, or at least undermine, congressional intent to conclude that the federal courts might nevertheless exercise federal-question jurisdiction and provide remedies for violations of [the FDCA] solely because the violation of the federal statute is said to be [an element of a claim] under state law. . . .

Id. at 812. State creation of extra-statutory FDCA "remedies" is equally suspect. "When we conclude that Congress has decided not to provide a particular federal remedy, we are not free to 'supplement' that decision in a way that makes it 'meaningless.' " *Id.* at 812 n.10 (citations omitted).

Congressional intent is at least as important to preemption as to determination of federal jurisdiction. "[T]he purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992) (citation and quotation marks omitted). With *Medtronic*, the "assumption" in *Merrell Dow* of no private FDCA rights of action crystallized into an established legal rule. *See, supra*, at p. 13. Allowing "fraud on the FDA" claims to masquerade as "state law" thus "flout[s] congressional intent." *Merrell Dow*, 478 U.S. at 812. Therefore such claims are preempted.

Ad hoc reexamination of FDA decisions by lay juries in state-law actions around the country is contrary to the regulatory structure Congress intended. Even when FDA concludes it has been defrauded, the implicated approval is not void *ab initio*. FDA retains discretion to impose a lesser sanction than removing a product from the market. *United States v. Chatterji*, 46 F.3d 1336, 1341 (4th Cir. 1995). The PLC seeks to "use the threat of damages to require [defendants] to do exactly what [FDA] is empowered to excuse." *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 326 (1981). The PLC wants state-law juries to disagree with FDA's 1998 rejection of the PLC's fraud allegations. The FDCA does not contemplate "a dual system of futile duplication of two authorities over the same subject matter." *California v. Federal Energy Regulatory Commission*, 495 U.S. 490, 502 (1990) (citation and quotation marks omitted). Preemption is necessary to preserve both FDA's exclusive enforcement powers and its prosecutorial discretion.

II. The *Medtronic* Decision Did Not Hold That "Fraud On The FDA" Claims Escape Preemption.

The court below did not purport to recognize a private FDCA action for "fraud on the FDA." Pet. App. at 13a. Rather, the court held, "[w]e see no inconsistency between the FDA having the exclusive prerogative of bringing actions to enforce the FDCA" and private plaintiffs "bring[ing] common-law fraudulent misrepresentation claims." *Id.* at 18a.

The error in this reasoning is that "fraud on the FDA" is fundamentally different than a traditional common-law fraud claim.

Traditional fraud is predicated upon a defendant, directly or indirectly, passing false information to a plaintiff, who detrimentally relies upon that information.[26] The PLC's complaints do not allege that any plaintiff, treating surgeon, or anyone outside FDA, knew of the allegedly false statements of "intended use" made to FDA, often many years before surgery.

Nor are tort actions based upon procedural irregularities. A "negligence *per se*" action will lie for violations of substantive safety standards.[27] Administrative guidelines, such as the content of administrative submissions, do not give rise to tort claims for their violation.[28] Procedural attacks upon federal administrative decisions are federal questions governed by the APA, *see, e.g.*, 5 U.S.C. §702; 28 U.S.C. §1331, and the PLC may continue to pursue that avenue. The truth of representations to FDA is for FDA to decide.

The court below also erred in employing a "presumption against preemption." Pet. App. at 18a. When Congress "legislate[s] . . . in a field which the States have traditionally occupied," there is a presumption against preemption. *Medtronic*,

26. *See* Restatement (Third) of Torts, Products Liability §9 & comment c (1997) (misrepresentation must be "in connection with the sale of a product"; reliance required); Restatement (Second) of Torts §402B & comment j (1965) (misrepresentation must be "to the public"; reliance required); Restatement (Second) of Torts §310 & comment c (1965) (misrepresentation must induce reliance, such as a third person's mistaken belief as to safety); Restatement (Second) of Torts §§537, 548 (1976) (must be reliance upon the misrepresentation).

27. *See* Restatement (Third) of Torts, Products Liability §4, comment a (1997) (violation claims limited to "final governmental edicts and directives . . . that establish binding safety standards").

28. *See* Restatement (Second) of Torts §288(a) (1965) (negligence *per se* not applicable to enactments that "protect the interests of the state or any subdivision of it as such"). Thus licensing statutes do not support negligence *per se*. *See Talley*, 179 F.3d at 161; R.P. Davis, *Lack of Proper Automobile Registration or Operator's License as Evidence of Operator's Negligence*, 29 A.L.R.2d 963 §5 (1953 & Supp. 2000) (collecting cases).

518 U.S. at 485 (plurality opinion). Such a presumption, however, "is not triggered when the State regulates in an area where there has been a history of significant federal presence." *United States v. Locke*, 120 S. Ct. 1135, 1147-48 (2000). There is hardly any area more remote from state-law concern than the policing of submissions to federal agencies by federally regulated persons. Any presumption here should favor preemption, since "one can assume that Congress or an agency ordinarily would not intend to permit a significant conflict." *Geier*, 120 S. Ct. at 1927.

The PLC's "fraud on the FDA" claims are dependent, not upon traditional tort reliance, but rather upon the claimed invalidity of FDA actions. The court below recognized this fact, but failed to appreciate its significance. *See* Pet. App. at 21a ("without Buckman's fraudulent representation, the FDA would not have given AcroMed a §510(k) clearance and that, absent a §510(k) clearance, AcroMed would not have access to the market"). Thus, the PLC's "fraud on the FDA" claims empower common-law juries to nullify administrative actions taken by FDA — by declaring the "absence" of those FDA actions.

The PLC does not request reconsideration of any FDA action regarding these devices upon a "truthful" record. Rather, the PLC wants juries to void FDA actions retroactively and to award damages. The conflict between this "tort" and a specific FDA requirement (here, clearance for marketing) imposed upon a specific device is total, because juries would be asked to treat standing FDA decisions as invalid. The conflict is also inherent, because unless the jury concludes that FDA decisions should be nullified, the PLC's claim cannot succeed. There was no such claim at issue in *Medtronic*.

Thus the court below should not have relied upon the rationale of the *Medtronic* plurality that the absence of private FDCA rights of action was "evidence of an intent *not* to preempt common law liability." Pet. App. at 15a (citing *Medtronic*, 518 U.S. at 487) (emphasis in original). The *Medtronic* plurality's observation was made in the context of rejection of an argument that §360k(a) preempted all state-law

claims. *Medtronic*, 518 U.S. at 487-89. That discussion is inapposite here, since the PLC has alleged numerous unpreempted claims such as design and warning defects. Nor did *Medtronic* involve any claim having nullification of an FDA action as an essential element. In construing a "splintered" decision like *Medtronic*, "the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977). The court below ignored this stricture, since nothing in *Medtronic* addressed or implicated "fraud on the FDA" claims.

"Fraud on the FDA" is not analogous to any claim at issue in *Medtronic*, and the lower court's decision would avoid even preemption appropriate under *Medtronic*. No member of this Court disagreed with Justice Breyer that "a federal MDA regulation requir[ing] a 2-inch wire" would preempt a state tort claim "that use of a more than 1-inch wire is negligent." 518 U.S. at 504 (Breyer, J., concurring). But the court below would deny preemption of the same if it alleged that the "2-inch" regulation was the product of fraud upon FDA.

In particular, "fraud on the FDA" is the polar opposite of the "identity of requirements" claim that *Medtronic* unanimously held was not preempted.[29] *Medtronic* addressed only an undeveloped allegation that the defendant "violated FDA regulations." 518 U.S. at 495. The state-law duties in *Medtronic* thus could have "parallel[ed] federal requirements." *Id.* Here, "fraud on the FDA" would allow state-law juries to set aside what the PLC claims are fraudulently obtained FDA clearances – despite FDA's investigation of these allegations and the Agency's decision that they merited no action. A greater divergence between the requirements of federal and state law would be difficult to envision.[30]

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29. 518 U.S. at 494-97 (opinion of the Court), 513 (O'Connor, J. concurring, joined by the Chief Justice and Scalia and Thomas, JJ.)).

30. The PLC's assertion of "violations" of FDCA procedures cannot conceal that "fraud on the FDA" seeks to overturn the substantive FDA decisions resulting from those procedures. Courts are "not bound by the name, description or characterization" of state law, "but will determine for [themselves] the practical impact of the law." *Hughes v. Oklahoma*, 441 U.S. 322, 336 (1979) (citation and quotation marks omitted).

MSD is a national seller of medical devices, and the *Orthopedic Bone Screw* litigation is equally nationwide in scope. After the Court of Appeals' decision, however, MSD faces the likelihood that the validity *vel non* of the FDA clearances for its devices – and thus its ability to market those devices at all – may vary from state to state, or even within a state, depending on conflicting verdicts of lay juries.

Collateral attacks upon FDA decisions threaten suppliers of medical devices and drugs with liability, not for defective products, but for marketing their products in reliance upon FDA decisions that state law cannot retroactively annul. Because subjecting all FDA regulated manufacturers to inconsistent state-law decisions on the basic issue of whether they can legally market their products was not what Congress intended when it enacted the FDCA, this Court should reverse the decision below and hold that "fraud on the FDA" tort claims are preempted.

III. "Fraud On The FDA" Claims Disrupt FDA Administration Of Federal Law.

Where state law "presents the prospect of interference with the federal regulatory power," there is preemption as long as the potential disruption is more than "hypothetical." *Schneidewind v. ANR Pipeline Co.*, 485 U.S. 293, 310 (1988) (citation and quotation marks omitted). Preemption arises from "conflict of rules of law, of remedy, and of administration." *San Diego Building Trades Council v. Garmon*, 359 U.S. 236, 242 (1959). Where an administrative agency is involved:

> Congress did not merely lay down a substantive rule of law. . . . It went on to confide primary interpretation and application of its rules to a specific and specially constituted tribunal and prescribed [] particular procedure[s]. . . . Administration is more than a means of regulation; administration is regulation. We have been concerned with conflict in its broadest sense; conflict with a complex

and interrelated federal scheme of law, remedy, and administration.

Id. at 242-43 (citation and quotation marks omitted).

In its *amicus curiae* brief in support of *certiorari*, the United States pointed out that "fraud on the FDA" claims "could produce undesirable practical consequences" hindering FDA's ability to function. Brief for United States as *Amicus Curiae* [on Petition for *Certiorari*], at 16. Those adverse consequences are not hypothetical. They have occurred in this very litigation.

Excessive involvement of FDA personnel in private litigation is not a risk — it is a certainty — where "fraud on the FDA" is claimed. Here, given FDA restrictions upon availability of Agency personnel in litigation,[31] the litigants first competed to hire as their experts former FDA employees who had participated in the regulatory matters at suit.[32] In and of itself, the potential of lucrative employment opportunities for FDA employees with "fraud on the FDA" litigants should such claims survive preemption could well bias how future FDA internal deliberations are conducted or remembered.[33]

The PLC then turned its attention to FDA permanent and "special government employees"[34] engaged in FDA's

31. *See* 21 C.F.R. §20.1; *Giza v. Secretary of HEW*, 628 F.2d 748, 749 (1st Cir. 1980). *See generally United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951) (administrative agencies may restrict litigants' access to agency personnel).

32. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1995 WL 925673 (E.D. Pa. May 5, 1995) (PTO 45) (allowing PLC to use contested FDA witness).

33. For example, a former FDA employee hired by the PLC characterized an FDA meeting with Petitioner Buckman dramatically differently than did FDA itself in documents obtained through the Freedom of Information Act ("FOIA"). *Compare* FDA internal memorandum regarding Buckman meeting (Exhibit 2 to "Christiansen Declaration" accompanying MDL Dkt. #221), *with* Declaration of Carl Larson, Ph.D, P.E. ¶¶37-39 (Exhibit 8 to MDL Dkt. #4955).

34. "Special government employees" are, *inter alia*, officers or employees of the executive branch or an independent agency of the United States retained, designated or employed to perform, with or without compensation, for limited periods, temporary duties either on a full- or part-time basis. 18 U.S.C. §202. The FDA Commissioner may appoint members of the scientific and medical communities as special government employees. 21 C.F.R. §14.31(d-e).

ongoing reclassification of pedicle screw spinal systems, and particularly to FDA personnel involved with the cohort study of those devices that was the single largest piece of scientific evidence supporting reclassification.[35]

In July, 1995, the PLC noticed the depositions of twelve special and four permanent FDA employees — including all five members of FDA's advisory committee reviewing pedicle screw spinal systems.[36] The PLC's notice (reproduced as Appendix "B") demanded that these FDA employees testify and produce documents concerning 28 topics, ranging from FDA's internal deliberations to each employee's "compensation" and "daily activities" for more than two years. App. "B" at 22a-25a. The United States sought protective orders forbidding or limiting most of these the depositions, MDL Dkt. ##475, 536, and produced sworn evidence that exposing FDA special employees to hostile litigation discovery harms FDA's ability to recruit people with the necessary expertise. MDL Dkt. #475, Exhibit D ¶¶9-11; Exhibits F-H.

The MDL court denied the government's motions, and allowed the disputed discovery as to all but one FDA employee. *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, 1995 WL 925670 (E.D. Pa. Aug. 10, 1995) (PTO 87); *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, slip op. ¶2 (E.D. Pa. Aug. 21, 1995) (PTO 92). Thus, the "fraud on the FDA" claims in this very litigation resulted in multiple depositions of FDA personnel

35. The cohort study was a private medical study conducted "with input from FDA." 63 Fed. Reg. at 40030 (Item 2); *see id.* at 40026 n.1 (describing study generally).

36. The PLC's notice is Exhibit A to the United States' brief seeking a protective order. MDL Dkt. #475. The permanent FDA employees were: Melkerson, Yahiro, Mishra, and Wilkerson; and the special FDA employees were: Murray, Morrey, Mayor, Benson, Whitecloud, Kane, Crawford, Yuan, Rangaswamy, Carty, Greenwald and Hanley. *Id.* at Exhibit C ¶2. Of these, the members of the Advisory Committee were: Murray (chairman), Greenwald, Hanley, Carty, and Rangaswamy. MDL Dkt. #299, Exhibit 75, at pp.2-3.

— including an entire FDA-created deliberative body — over the policy-related objections of FDA.

The history of MDL 1014 also demonstrates the idiosyncratic ways that "fraud on the FDA" litigation can harm FDA's ability to carry out its regulatory mission. Here, FDA became so enmeshed in MDL 1014 that the litigation repeatedly impinged upon its administrative review of pedicle screw spinal systems.[37] But the worst effect of the *Orthopedic Bone Screw* litigation was that discovery relating to the alleged FDA fraud undermined and ultimately defeated FDA's ability to keep promises the Agency had made to the medical community.

To obtain frank responses from cohort study participants about surgical success and complications, FDA promised these surgeons anonymity. 63 Fed. Reg. at 40030 (Item 2). The PLC used litigation discovery to overcome FDA's promise. Within days of FDA's October 4, 1995 announcement of its decision to reclassify the devices at suit, the MDL court ordered a copy of FDA's entire cohort study file turned over to the PLC, allowing redaction of only the identities of participating surgeons and patients. *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, slip op ¶2 (E.D. Pa. Oct. 16, 1995) (PTO 147). The PLC then argued that the participants' names had to be released so it could file public comments with FDA opposing reclassification. MDL Dkt. #975. FDA sought to protect its promise of confidentiality, MDL Dkt. #1153, and temporarily succeeded in retaining the anonymity of most surgeons. *In re Orthopedic Bone Screw Products Liability Litiga-*

37. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op. at 1 (E.D. Pa. Jan. 2, 1996) (PTO 188) (FDA extends public comment period to accommodate MDL court); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, at Exhibit (E.D. Pa. May 28, 1996) (PTO 363) (FDA required to report to MDL court on audit of cohort study); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1996 WL 938334, at *1 (E.D. Pa. Jun. 6, 1996) (PTO 394) (FDA ordered to turn over confidential identities of cohort study participants to MDL court); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1999 WL 455667, at *7 (E.D. Pa. Jul. 1, 1999) (FDA ordered to report to MDL court in writing about its handling of PLC citizen petition). FDA also had to respond to multiple FOIA requests.

tion, MDL 1014, 1995 WL 764580, at *5 (E.D. Pa. Dec. 15, 1995) (PTO 179) (surgeon identities not disclosed except those who testified before the FDA advisory committee).

The PLC promptly penetrated the participating surgeons' anonymity by cross-referencing unredacted birth and surgery dates from FDA's file with dates and surgeon names supplied by the plaintiffs.[38] The MDL court permitted the PLC first to "break" FDA's code, *In re Orthopedic Bone Screw Products Liability Litigation*, MDL 1014, slip op. at 7-8 (E.D. Pa. Feb. 14, 1996) (PTO 254), and then to question participating surgeons in their depositions about submissions that FDA had promised would be kept anonymous and confidential.[39]

This litigation thus has damaged the medical community's confidence in FDA's ability to keep promises necessary to obtain physician cooperation with the Agency — something FDA "regrets." 63 Fed. Reg. at 40039 (Item 42).[40] As FDA has no power to conduct its own clinical studies, *see, supra*, at p. 10, the Agency needs to be able to enlist the medical community's help in future efforts to determine the safety and effectiveness of medical devices and drugs. The Agency's regu-

38. *See* MDL Dkt. #1184, at p.6 (PLC describes methodology), pp.18-24 (PLC chart indicating identification of 26 participating surgeons); MDL Dkt. #3720, at pp. 686-93 (same).

39. *See* "Decision and Recommendation No. 18 of Special Discovery Master (as to Deposition of Dr. Ensor Transfeldt)," MDL Dkt. #5636 (describing one example of PLC deposition about supposed "discrepancies" in surgeon's cohort study submissions). MSD does not know the total number of participating surgeons who lost FDA-promised confidentiality, but the MDL court ultimately ended discovery regarding the cohort study because of "the PLC's access to this data." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, 1998 WL 964495, at *2 (E.D. Pa. Nov. 3, 1998) (PTO 1601).

40. FDA also inadvertently disclosed participating surgeon identities to the PLC in discovery, although the PLC denies taking advantage. *See In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, slip op at 1-2 (E.D. Pa. Oct 26, 1995) (PTO 157) (ordering PLC not to use mistakenly produced FDA material); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014 (E.D. Pa. Jan. 16, 1996) (PTO 193) (ordering return of material); *but see, In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL 1014, at Exhibit ¶7 (E.D. Pa. Jan. 4, 1996) (PTO 191) (PLC admits retaining digital copy of FDA's inadvertent production after returning hard copies).

latory efforts will be hindered if FDA cannot keep confidentiality promises to those whose help it needs — and if physicians who assist FDA in those efforts can be exposed to litigation such as this.

Legal recognition of "fraud on the FDA" would have other adverse practical ramifications. *First*, FDA regulations only require submission of one "intended use" to support device clearance. *See* 21 C.F.R. §807.92(a)(5). The PLC's FDA fraud claim effectively demands submission to FDA of every potential use known to an applicant — forcing FDA to wade through information it neither wants nor needs.

Second, suppliers of medical devices and drugs could not inform physicians of medical advances that utilize their products, as permitted by the FDCA, 21 U.S.C. §360aaa, without fear of exposing their FDA-recognized "intended uses" to state-law challenge as "fraudulent."

Third, because fraud, rather than a defective product, is the basis of the claim, "fraud on the FDA" could be asserted by competing device and drug companies to interfere with their competitors' products — thereby embroiling FDA not only in personal injury litigation, but also in the competitive machinations of regulated manufacturers. *Cf. Medtronic*, 518 U.S. at 494 & n.14 (discussing "procompetition" purpose of FDA clearance process at issue in this litigation).

CONCLUSION

Because "fraud on the FDA" claims seek state-law nullification of in-force FDA administrative actions, such claims necessarily seek to impose "differing" requirements under 21 U.S.C. §360k(a) and inherently conflict with and second-guess FDA decisions. For all of the above reasons this Court should reverse the United States Court of Appeals for the Third Circuit and hold that "fraud on the FDA" claims are both expressly and impliedly preempted by federal law.

Respectfully submitted,

STEPHEN S. PHILLIPS*
Special Counsel for
MEDTRONIC SOFAMOR DANEK, INC.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-2695

JAMES M. BECK
*Counsel of Record**
MICHELLE HART YEARY
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth & Arch Streets
Philadelphia, PA 19103-2799
(215) 981-4000

Counsel for Amicus Curiae Medtronic Sofamor Danek, Inc.

Dated: September 13, 2000

**Member of the Supreme Court Bar*

APPENDICES

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

John Lee Ramey and Candice Ramey,
Plainfiffs,

v.

Danek Medical, Inc.; Sofamor-Danek Group, Inc.; Warsaw Orthopedic, Inc.; Eduardo Luque; Charles E. Johnston, II; Richard Ashman, Ph.D.; Gary Lowery; George Rapp; Ensor Transfeldt; John A. Herring; Thomas Whitecloud, III; Thomas A. Zdeblick; Youngwood Medical Specialties, Inc., f/k/a/ National Medical Specialty, Inc., f/k/a/ Stuart Medical Specialty, Inc.; Stuart Medical, Inc., f/k/a/ Stuart Drug and Surgical Supply, Inc.; Texas Scottish Rite Hospital for Crippled Children; American Academy of Orthopaedic Surgeons; North American Spine Society; Scoliosis Research Society; Spinal Science Advancement Foundation; Acromed Corporation, Charter No. 614043; Acromed Corp. (Now Acromed Corporation, Charter No. 614043); Acromed Corporation, Charter No. 816942; Acromed, Inc., Charter No. 811415; Acromed Incorporated (Now Acromed Inc., Charter No. 811415); Acromed Incorporated, Charter No. 816943; Acromed Holding Corporation, Charter No. 811416; Acromed Corporation (Now Acromed Holding Corporation, Charter No. 811416); Ace Medical Company; Advanced Spine Fixation Systems, Inc.; Cross Medical Products, Inc.; DePuy-Motech, Inc.; Smith & Nephew Richards, Inc.; Sofamor, S.N.C.; Sofamor, Inc.; Synthes (U. S.A.); Synthes, Inc.; Synthes North America, Inc.; Synthes; A.G.; Zimmer, Inc.,
Defendants.

MDL 1014 CIV. NO. 96-422

D. MD. CIV. NO. 95 CV 3194

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT

* * *

3. On March 1, 1993, Dr. A.H. Dudley performed surgery on Plaintiff at Children's Hospital in Baltimore, Maryland and implanted a Danek pedicle screw fixation device known as the Luque device in Plaintiffs spine.

* * *

Count I: Fraud (on the FDA)

84. Plaintiff repeats and realleges each and every allegation set forth in the paragraphs above and further alleges the following.

85. The claims made in Count I of this Complaint are made against Danek and Sofamor-Danek.

86. The Luque II plate and screw device was developed by Eduardo Luque ("Luque") specifically for use in spinal surgery involving the lower back. The device consists of plates and screws which are intended to be attached to the lumbar spine with screws inserted posteriorly through the lumbar pedicles in order to provide a means of internal stabilization in connection with spinal fusion surgery.

87. On March 26, 1986, Warsaw Orthopedic submitted a 510(k) notification to the FDA for the Luque II device which was described as the "Interpeduncular Segmental Fixation System."

88. Less than two months later, on May 6, 1986, the FDA determined that the device was a Class III device which was not substantially equivalent to any pre-enactment device and which, therefore, could not be sold in the United States without a premarket approval based data developed in prospective clinical trials pursuant to an approved IDE. In explaining this decision, the agency stated that the decision was based on the fact that there had not been adequate demonstration that there was a pre-amendment device with a design substantially equivalent to The Luque System and on the fact that it posed potential risks not exhibited by other spinal fixation systems, such as:

"1. greater chance of neurological deficit due to imprecise screw placement or the event of screw failure;

2. pedicle fracture during placement of the screw;

3. soft tissue damage or inadequate fusion due to bending or fracture of device components; and

4. greater risk of pseudoarthrosis due to instability of design."

89. Determined to immediately sell the Luque II device for spinal fixation, Danek conceived and implemented an unlawful and deceptive scheme to bring the Luque II device to market without premarket approval and without the development of the kind of safety and efficacy data necessary to obtain such premarket approval.

90. The unlawful plan contemplated that:

(a) Danek would fraudulently seek 510(k) clearance of the components of the Luque II system as "bone plates" and "bone screws" for use in repairing fractures of the long bones even though the sole intended use of the Luque II system was in spinal applications;

(b) Once clearance from the FDA was obtained, Danek would contend that the FDA determination of substantial equivalence constituted official notification from the FDA that the devices were safe and effective and that such devices could be introduced for commercial use; and

(c) Consistent with Danek's goal to sell the Luque II device in interstate commerce for its intended use as a pedicle screw fixation device, Danek would promote the device by using physicians such as Luque to train other physicians in spinal applications of the Luque II device.

91. Using this approach, on June 5, 1986 Danek submitted a 510(k) notification for the same device components which made up the ISF system for which 510(k) clearance had previously been denied.

92. In the June 5, 1986 submission, the system components were described as "the Warsaw Orthopedic Bone Plate and Cancellous Bone Screw."

93. The notification claimed that "[t]he screws are designed for use in all fractures treated with two or more cancellous lag screws, such as intracapsular fractures of the hip and femoral condyle and tibia plateau fractures."

94. With respect to the plate components, the notification stated that "[s]pecific application is of course within the purview of the physician, but the use of the device in conditions such as long bone osteotomy, pelvic fracture and arthrodesis of the knee and/or ankle is obvious."

95. Subsequent correspondence with the FDA on behalf of Danek in connection with the notification emphasized that the device was intended for general orthopedic use in the long bones and not for pedicle fixation.

96. A July 2, 1986 letter written on behalf of Danek to the FDA in connection with the notification falsely stated that the Warsaw screws were "intended for use in the treatment and management of orthopedic injuries or conditions that in the view of the physician will benefit from the application of metallic screws or metallic plates and screws. Generally, this means for the repair of osseous fractures or conditions using screws having enhanced holding power in the cancellous bone."

97. Further misrepresentations appear in an August 1, 1986 letter written on behalf of Danek to the FDA regarding use of the cancellous bone screws, in which it was stated that "[t]he manufacturer intends that the screw will be used to treat fractures of cancellous bone."

98. In reasonable and justifiable reliance on the misrepresentations made regarding the intended use of the plates and screws which were the subject of the June 5, 1986 510(k) notifications, the FDA cleared these components as substantially equivalent to pre-amendment devices.

99. The representations made by Danek in obtaining these 510(k) clearances were intentionally false and

misleading. L.D. Beard, who at the time was the President and Chief Executive Officer of Danek, conceded at a deposition that the intended use of the bone plates and bone screws which were the subject of the June 5, 1986 510(k) notifications was not for repair of fractures of the long or flat bones as set forth in those 510(k) notifications. Rather, he admitted that the sole intended use of the system and system components was for use in spinal applications (i.e., pedicle screw fixation) and that the only reason why the FDA was told otherwise was so that clearance could be obtained so that the device could enter the market where Danek intended to promote and sell it only as a pedicle screw/spinal plate fixation system.

100. At the time the FDA made its substantial equivalence determination with regard to the Luque II device (which was presented to the FDA as "Warsaw Orthopedic Bone Plates and Cancellous Bone Screws"), it was ignorant of the fact that Danek had misrepresented the intended use of the Luque II Plates and Screws and that the sole intended use of the device components was as pedicle screws and spinal plates assembled as a spinal fixation system.

101. On June 27, 1986, an application was submitted for Danek to conduct clinical trials of the Luque Intrapeduncular Segmental Fixation System pursuant to the Investigational Device Exemption provisions of the Food, Drug and Cosmetic Act. The stated purpose of the IDE application was to develop data on the safety and effectiveness of the Luque II device for pedicular fixation.

102. The FDA granted approval to conduct the IDE trials involving a limited number of physicians and institutions.

103. However, the Luque II IDE failed to generate sufficient information on safety and efficacy to permit the FDA to grant premarket approval of the device for its intended use as a pedicle screw fixation device.

104. Nevertheless, Danek marketed and promoted the Luque II device on a massive basis outside of the IDE trial solely for its intended use as a pedicle screw fixation device.

105. Danek also manufactures, markets, distributes and sells the Texas Scottish Rite Hospital ("TSRH") spinal system. This instrumentation system was developed by Richard Ashman, Ph.D., ("Ashman"), John Herring, M.D. ("Herring") and Charles Johnston, M.D. ("Johnston") at the Texas Scottish Rite Hospital in Dallas, Texas.

106. The TSRH system employs a pair of rods arranged along the vertical axis of the spine which are connected to the vertebrae with hooks, screws or both.

107. Danek did not seek clearance from the FDA to market the screw components of the TSRH system for use in the pedicles of the lumbar vertebrae which, anatomically, lie above the bony base of the spine known as the sacrum.

108. However, it did seek 510(k) clearance for sacral application of the TSRH screws.

109. On September 2, 1988 a 510(k) notification was submitted to the FDA for what was described as TSRH "sacral screws."

110. Based on the representation that these screws were intended to be used in the sacrum, the FDA determined, on April 6, 1989, that the TSRH sacral screws were substantially equivalent to pre-enactment device components.

111. On September 12, 1990, Danek submitted a 510(k) notification to the FDA for the TSRH Variable Angle Sacral Screw.

112. The notification stated that the Variable Angle Sacral Screw was a modification of the TSRH sacral screw and followed the same intended use.

113. Based on the representation that these screws were to be used in the sacrum, the FDA determined on January 22, 1992 that TSRH Variable Angle Sacral Screw was substantially equivalent to a pre-amendment device.

114. The representations made in the 510(k) notifications to the FDA concerning the intended use of TSRH sacral and variable angle sacral screws were intentionally false and misleading.

115. At the time Danek submitted these 510(k) notifications, Danek intended that the screws which were labeled as "sacral screws" would be used by surgeons in the pedicles of the lumbar spine. Indeed, Danek funded a book which was authored by the developers of the system concerning its use. The book was specifically written to go along with the system as part of the system itself. It was to serve as a "cornerstone" for courses and workshops concerning the use of the system and "as a way to stimulate users' interest in purchasing and employing the instrumentation." One Chapter of this book, Chapter 5, is dedicated exclusively to a discussion involving the use of TSRH "sacral screws" in the pedicles of the lumbar spine in order to create a fixation construct for treatment of degenerative spinal instability. The text and illustrations in this regard are unmistakable. Chapters 4, 6 & 7 of the book also describe the use of TSRH screws in the lumbar pedicles. These chapters together account for over half of the book.

116. Consistent with this, Danek expressly viewed the TSRH system as a "pedicle screw fixation system."

117. Danek did request and receive approval to conduct IDE clinical trials involving 10 institutions and 240 subjects in order to obtain clinical data on the safety and efficacy of pedicle screw fixation with the TSRH system.

118. The TSRH pedicle screw IDE did not develop sufficient data to result in a successful application for premarket approval.

119. Nevertheless, Danek marketed and promoted the TSRH device on a massive basis outside of its IDE trial for its intended use as a pedicle screw fixation device.

120. Danek also manufactures, distributes and sells the so-called "Dyna-Lok" Spinal Fixation System. The system is a plate and screw device.

121. On September 7, 1991 Danek submitted at [sic] 510(k) notification for the Dyna-Lok Fixation System. The application falsely stated that the device was substantially equivalent to the Warsaw Bone Plate, now called the Danek

Plate, and that the bone screws used in the Dyna-Lok device were substantially equivalent to the TSRH Sacral Screw.

122. In reliance on Danek's representations concerning the intended use of the Dyna-Lok device, on December 17, 1992, the FDA determined that the device was substantially equivalent to pre-amendment devices.

123. Danek's 510(k) notification for the Dyna-Lok Fixation System misrepresented the intended use of the device. The device was designed and intended exclusively for use as a pedicle screw fixation device.

124. All of the misrepresentations made by Danek to the FDA as set forth in Count I of this Complaint were made intentionally to deceive the FDA and to induce it to issue 510(k) clearances for the Luque II, TSRH, and Dyna-Lok devices and device components in order to provide Danek with a pretext to claim that the devices could be lawfully introduced into interstate commerce.

125. The FDA was ignorant of the fact that these devices and device components were intended by Danek for use as pedicle screw fixation devices.

126. Were it not for these fraudulent acts and statements, the FDA would not have issued 510(k) clearances for Danek's pedicle screw fixation devices and device components for any purposes, the devices would not have been introduced into interstate commerce, and the Plaintiff would not have been exposed to the dangerous device which was surgically implanted in the Plaintiff.

127. The FDA, Plaintiff and Plaintiffs' implanting physicians relied upon Danek to make truthful statements to the FDA in its 510(k) notifications regarding the intended use of the devices at issue so that Plaintiff would not be implanted with a dangerous medical device that was never proven to be safe and effective for the use for which it was intended, i.e., pedicle screw fixation.

128. As a direct and proximate result of Danek's misrepresentations as set forth in Count I of this Complaint, Plaintiff suffered severe and permanent physical harm

including injuries to his spine, spinal nerves, spinal nerve roots and surrounding tissues, cells, nerves and vascular structures. As a result, Plaintiff has in the past and will in the future suffer a loss of earnings, an impairment in earning capacity, physical pain, mental anguish, emotional distress, permanent disability, liabilities for medical and rehabilitative expenses and other forms of damage, loss and harm.

* * *

B. The Intercompany/Association Conspiracy

* * *

238. By 1992, the manufacturers and sellers who marketed pedicle screw fixation devices in violation of federal law and the physicians and professional associations they conspired and acted in concert with expressed a need to find a means to avoid criminal prosecution and civil liability in connection with their past unlawful promotion of pedicle screw fixation devices and to legitimize the sale of such devices in the future.

239. In furtherance of the original goals of the intercompany/association conspiracy and as a means to avoid liability for past wrongful acts, those who participated in the intercompany/association conspiracy adopted and implemented a two-part scheme.

240. First, all of the members of the intercompany/association conspiracy agreed to the creation, funding, and support of a trade association which was named the Spinal Implant Manufacturers Group ("SIMG"), and a "Scientific Committee" to conduct a "Cohort Study" of pedicle screw fixation in a fraudulent and misleading manner and to use the "results" of this deceptive and misleading study:

(a) to achieve reclassification of pedicle screw fixation devices so that they could be legally marketed without the successful completion of prospective clinical trials and/or premarket approval;

(b) to avoid criminal prosecution for illegal sales and distribution of pedicle screw fixation devices; and

(c) to provide "scientific" evidence for use as part of a defense to litigation in which patients claimed that they suffered harm as a result of the use of pedicle screw fixation devices.

241. Pursuant to this scheme, data regarding the outcome of patients treated for spinal fracture and degenerative spondylolisthesis was gathered by SIMG, the Scientific Committee, AAOS, AANS, SRS, and NASS from spine surgeons who were selected to participate in the study; the data were received and analyzed by Biometric Research Institute, Inc. ("BRI"); and the results of the study were reported to an FDA advisory panel on July 22, 1994 and in a special issue of *Spine* magazine which was published on October 15, 1994.

242. Pursuant to the plan adopted by the members of the intercompany/association conspiracy, the manner in which the Cohort Study was conducted and reported was intentionally deceptive and materially misleading in that, among other things:

(a) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, the professional societies which designated representatives to serve on the Scientific Committee which was responsible for conducting the study (AANS, AAOS, SRS, and NASS), had significant financial relationships with the manufacturers and sellers of the pedicle fixation devices that were the subject of the Cohort Study which were not disclosed when the results of the study were reported;

(b) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, each of the members of the Scientific Committee which claimed responsibility for conducting the Cohort Study had a significant financial relationship with manufacturers of pedicle screw fixation devices, which became substantially

more generous on completion of the study. This circumstance was concealed from those to whom the study was reported.

(c) In reporting the results of the study, it was claimed that the study represented an "independent" analysis of the safety and efficacy of pedicle screw fixation. However, Hansen Yuan, M.D., who was chairman of the Scientific Committee which claimed responsibility for conducting the study was negotiating with two major pedicle screw manufacturers to license a new pedicle screw fixation device while the study was proceeding. Those manufacturers had made offers to pay him as much as one million dollars in cash and a percentage royalty worth as much as twenty-five million dollars for the license, making it explicit that the amount which Dr. Yuan would realize under these proposed arrangements was directly dependent on whether the FDA reclassified pedicle screw fixation devices as a result of the Cohort Study. Dr. Yuan concealed these transactions when the results of the Cohort Study were reported. Moreover, when Dr. Yuan was questioned concerning these transactions at a deposition and at a hearing, he falsely stated that he did not engage in these negotiations until the Cohort Study had been completed and gave false and misleading information concerning the agreement which he ultimately entered into for the licensing of the pedicle screw fixation system.

(d) In presenting the results of the Cohort Study to the FDA's advisory panel, the Scientific Committee represented that a sample of the Cohort study data was "assessed by an independent auditor pursuant to a plan which was based on a blinded, random site selection process" which demonstrated that the submitted data were accurate when, in fact, the only "audit" which was done was a revisit of five sites by a masters-level employee of Dr. Yuan, who later

admitted significant inaccuracies in data reporting and other material failures to comply with the study protocol.

(e) SIMG and the Scientific Committee adopted and implemented a policy to destroy virtually all documents related to the Cohort Study before the study was reported to the FDA advisory panel in violation of an existing document preservation order entered by a federal court and with the intent to destroy evidence concerning the manner in which the Cohort Study was created and implemented;

(f) BRI, which received and analyzed the Cohort Study data was directed by Order of the United States District Court for the Eastern District of Pennsylvania to produce all computer diskettes and documents in its possession concerning the study. Not only did BRI fail to comply with that order but it also falsely stated, under oath, that the computer diskettes in its possession concerning the study had technical defects which prevented it from making usable copies, that its computer backup system containing Cohort Study data had mysteriously "crashed," destroying the information encoded therein, and that it had virtually no documents in its possession concerning this study. After a lengthy hearing, however, it was "discovered" that BRI had usable computer diskettes which could be copied, that there was no "crash" of the BRI computer backup system and that BRI had boxes full of documents which were properly subject to production;

(g) In presenting the results of the Cohort Study, it was represented that the Cohort Study was "conducted" by the Scientific Committee and that the study data was collected or analyzed by the Scientific Committee when, in fact, the Scientific Committee was not familiar with the manner in which the study data was processed, the way in which it was verified, or the procedures which were developed and applied with regard

to missing, incomplete, and inconsistent data and did not perform or understand the statistical treatment of the Cohort Study data;

(h) The Cohort Study was purportedly designed to demonstrate the difference between the outcome of patients treated with pedicle screw fixation and the outcome of patients who were treated for the same conditions by other methods. However, the study intentionally distorted that comparison by excluding data from physicians who infrequently used pedicle screw fixation and frequently used other methods to treat the conditions under consideration;

(i) The physicians who participated in the study inaccurately reported the post-operative conditions of patients who underwent pedicle screw fixation surgery, selectively excluded data for patients who should have been included in this study and selectively included the data from patients who should have been excluded from the study;

(j) The study exacerbated the potential for reporting and selection bias by providing that data be submitted anonymously by spine surgeons; and

(k) In reporting the results of the study the fusion outcome in patients who received pedicle screw fixation surgery was falsely inflated in relation to the fusion rate achieved in patients who underwent fusion surgery without pedicle screw fixation.

243. To this date, Defendants involved in the Danek and intercompany/association conspiracies are attempting to use this fraudulent and misleading Cohort Study as a means of escaping liability in this and related litigation.

244. Beginning in the Spring of 1993, as the second aspect of the effort to achieve the legal marketing status for pedicle screw fixation devices through fraudulent and deceptive means, Danek and other manufacturers and sellers of pedicle screw fixation devices engaged in a collaborative industry-physician effort to deceive the FDA with respect to

the commercial use of a Harrington lag screw for pedicle fixation prior to 1976 in order to persuade the FDA that pedicle screws were substantially equivalent to pre-enactment devices and therefore deserving of 510(k) clearance without analysis of safety or efficacy.

245. Specifically, in furtherance of the goals of the intercompany/association conspiracy, AcroMed, Danek, Sofamor and Zimmer agreed to obtain fraudulent and false documents and testimony purporting to prove that Zimmer had made and sold a commercially available pedicle screw in the United States prior to May 28, 1976 and submit such documents and testimony to the FDA to secure 510(k) approval for the Danek TSRH system.

246. AcroMed, Danek, Sofamor and Zimmer knew that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

247. In fact, Zimmer's Director of Regulatory Affairs knew as early as November 1987 that the position of the FDA was that Zimmer had not made and sold a pedicle screw in the United States prior to May 28, 1976 that would meet the pre-requisites of 510(k) clearance.

248. Zimmer knew on or before May 20, 1992 that other manufacturers were "pursuing reclassification to pre-enactment status based upon some old Zimmer drawings found in a surgeon's files."

249. Rick Treharne of Danek called Michael Mayock of Sofamor, who was a former Zimmer employee, and requested that Mayock prepare an affidavit to be submitted with the Danek TSRH 510(k) application claiming falsely that Mayock had personal knowledge of a pre-enactment sale in the United States of a Zimmer pedicle screw.

250. Treharne and Mayock drafted numerous revisions of a proposed affidavit until Treharne composed and sent Mayock a document described by Treharne as the "perfect affidavit," which Mayock executed.

251. Mayock obtained approval from Sofamor before executing this "perfect" affidavit and another affidavit and then transmitted the same to Sofamor.

252. Mayock claimed in his affidavit that Zimmer made a pedicle screw product prior to May 28, 1976 that would meet the prerequisites of 510(k) approval, asserting falsely that Zimmer shipped a pedicle screw made by Zimmer in the United States to Zimmer distributor Keith Bartow, who then sold the screw to a Mexican doctor named Luque.

253. Keith Bartow did not sell pedicle screws made by Zimmer in the United States to Dr. Luque prior to May 28, 1976.

254. In fact, Keith Bartow did not even meet Dr. Luque until the early 1980's.

255. Danek Chief Executive Officer Beard called Zimmer President Ron Davis and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

256. Zimmer President Ron Davis instructed Zimmer General Counsel Timothy Wendt to conduct such research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

257. AcroMed Director of Regulatory Affairs Christianson also called Zimmer General Counsel Timothy Wendt and requested that Zimmer perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

258. In addition, Danek employee Bailey Lipscomb or Danek employee Rick Treharne called Zimmer's Director of Regulatory Affairs Max Sherman and requested that Zimmer conduct research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

259. Sherman has testified that Zimmer had a policy against giving assistance to other manufacturers by providing them with supporting documents for 510(k) applications.

260. Nevertheless, Wendt ordered Zimmer employees to perform research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

261. Zimmer did not charge Danek for its research of pre-1976 pedicle screw usage to assist in Danek's TSRH 510(k) application.

262. For pre-amendment status, FDA Compliance Policy Guide 7124.19 requires the following: (1) at least one United States sale pre-May 28, 1976 of a product made in the United States; (2) catalogue advertising; and (3) no research support. To prove the first point, the FDA requires either invoices or an affidavit explaining their absence.

263. Wendt executed two affidavits to be submitted to the FDA to assist in Danek's TSRH 510(k) application, explaining the absence of invoices purportedly proving at least one United States sale of a Zimmer pedicle screw pre-May 28, 1976.

264. Zimmer employee Gary Tanner prepared an affidavit to be executed by former Zimmer employee Ralph Welling that repeatedly used the term "pedicle screw" in reference to purported pre-May 28, 1976 screw usage by Zimmer, even though Welling had never before used the term "pedicle screw" or even heard such term before seeing his proposed affidavit.

265. Tanner prepared an affidavit to be executed by Ralph Welling that referenced purported pre-May 28, 1976 "pedicle screws" shipments and usage even though Welling had no personal knowledge whatsoever regarding whether or not the referenced screws were actually manufactured, sold or used.

266. The affidavits by Mayock, Wendt and Welling were essential to convince the FDA to approve the Danek TSRH 510(k) on the basis that they purportedly established that there was a United States pre-May 28, 1976 sale of a Zimmer "pedicle screw."

267. AcroMed, Danek, Zimmer and Sofamor knew that the factual claim in the Danek TSRH 510(k) filing that Zimmer made and sold a commercial pedicle screw in the United States that was not involved in research prior to May 1976 was false.

268. Indeed, Zimmer filed a "Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims And Zimmer, Inc.'s Brief In Support Of Supplemental Motion For Summary Judgment On The Plaintiffs' Conspiracy Claims" (hereinafter "Supplemental MSJ") on or about March 15, 1996 in MDL 1014, providing in pertinent part that:

(a) "Zimmer has never marketed any device which includes a screw intended for use in the lumbar pedicles" (p. 5);

(b) "Zimmer has never marketed a pedicle screw fixation system for use in the United States" (p. 10);

(c) "Zimmer does not now and has never marketed a spinal device which includes a screw intended for use in the lumbar pedicles of the spine" (p. 11);

(d) "Zimmer did not even have a product in the pedicle screw market" (p. 16);

(e) "The undisputed fact is that Zimmer did not have a product to sell in that market [pedicle screws]" (p. 17);

(f) "Zimmer never marketed a device that included a screw intended for use in the lumbar pedicles" (p. 18); and

(g) "Zimmer does not market a pedicle screw device" (p. 25).

269. Neither AcroMed, Danek, Sofamor nor Zimmer advised the FDA, and the FDA did not know, that Zimmer asserted that it "never marketed a pedicle screw fixation system for use in the United States," in direct conflict with the position set forth in the Danek TSRH 510(k) application.

270. Danek's Lipscomb and AcroMed's Christianson flew to Kansas together and collaborated on additional research for the Danek TSRH 510(k) application.

271. Sofamor employee Mayock testified that the joint research effort by AcroMed, Danek, Sofamor and Zimmer was "like a loose confederation."

272. Zimmer's Max Sherman stated in a July 14, 1989 memorandum that 510(k) approval for portions of Zimmer's

spinal implant system "would be a good defense item for litigation. (It would indicate Zimmer developed PSI using proper approval procedures.)"

273. AcroMed stated in a May 15, 1995 News Release (TMI 00686) that its first 510(k) clearance would "seriously undercut those allegations" by Plaintiffs "in the pending products liability litigation against AcroMed."

274. In 1995, Danek submitted a 510(k) notification requesting clearance to market pedicle screws for use in its TSRH system. The claim of substantial equivalence to a pedicle screw device in commercial distribution prior to 1976, which was necessarily required to obtain 510(k) clearance, was based primarily on the Mayock and Wendt affidavits, the former of which was overtly false, and the other, materially misleading.

275. Based on and in reliance on the representations and affidavits contained in Danek's 510(k) submission, on January 20, 1995, the FDA announced its determination that it had cleared pedicle screws pursuant to the Danek 510(k) premarket notification for limited indications. Subsequent clearances were granted to other manufacturers including AcroMed, SNR and Cross based on the Danek clearance.

* * *

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1014
THIS DOCUMENT RELATES TO ALL ACTIONS	:	

NOTICE OF DEPOSITIONS

PLEASE TAKE NOTICE that plaintiffs in the above-entitled action will take the depositions, upon oral examination, of the following persons on the dates, at the times and in the places listed. The depositions are being taken pursuant to Paragraph 2 of Pretrial Order No. 51. At each deposition, each witness shall be required to produce those documents listed in Schedule "A" to this Notice. The depositions shall take place before a Notary Public and shall be stenographically transcribed and may also be recorded by videotape.

Name of Deponent	Date and Time of Deposition	Place of Deposition
David A. Murray	Monday, July 31, 1995 - 9:30 A.M.	Sheraton University Hotel and Conference Center 801 University Avenue Syracuse, NY
Paula Wilkerson	Monday, July 31, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Bernard F. Morrey	Tuesday, August 1, 1995 - 9:30 A.M.	Raddison Plaza Hotel 150 S. Broadway Rochester, MN 55904
Michael B. Mayor	Tuesday, August 1, 1995 - 9:30 A.M.	Hanover Inn Main & Wheelock Streets Hanover, NH 03755
Daniel R. Benson	Wednesday, August 2, 1995 - 9:30 A.M.	Red Lion Hotel 2001 Point West Way Sacramento, CA

Name of Deponent	Date and Time of Deposition	Place of Deposition
Thomas Whitecloud	Wednesday, August 2, 1995 - 9:30 A.M.	Cummings, Cummings & Dudenhefer 416 Gravier Alison House New Orleans, LA 70130
Mark Melkerson	Thursday, August 3, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
William J. Kane	Thursday, August 3, 1995 - 9:30 A.M.	Hines, Mili & Olson 700 North Star East 608 Second Avenue South Minneapolis, MN 55402
Nirmal Mishra	Friday, August 4, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Curtis Dickman	Friday, August 5, 1995 - 9:30 A.M.	Fountain Suites 2577 West Greenway Rd. Phoenix, AZ
Martin Yahiro	Monday, August 7, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Alvin Crawford	Monday, August 7, 1995 - 9:30 A.M.	Waite, Schneider, Bayless and Chesley Co., L.P.A. 1513 Central Trust Tower Cincinnati, OH 45202
Hansen Yuan	Tuesday, August 8, 1995 - 9:30 A.M.	Sheraton University Hotel and Conference Center 801 University Avenue Syracuse, NY
Steven Mardjetko	Tuesday, August 8, 1995 - 9:30 A.M.	Much, Shelist, Freed, Denenberg & Amend 200 North LaSalle Street Suite 2100 Chicago, IL 60601
Thomas Zdeblick	Wednesday, August 9, 1995 - 9:30 A.M.	Edgewater Hotel 666 Wisconsin Avenue Madison, WI
Leela Rangaswany	Wednesday, August 9, 1995 - 9:30 A.M.	Conway, Crowley & Hugo 4 Fameuil Hall Marketplace Boston, MA 02109

Name of Deponent	Date and Time of Deposition	Place of Deposition
Steven Garfin	Thursday, August 10, 1995 - 9:30 A.M.	Tschirn & Thomson 7825 Fay Avenue Suite 340 LaJolla, CA 92037
Claudia Thomas Cartie	Tuesday, August 10, 1995 - 9:30 A.M.	Latham Hotel 612 Cathedral Street Baltimore, MD
Seth Greenwald	Friday, August 11, 1995 - 9:30 A.M.	Weisman, Goldberg & Weisman 1600 Midland Building Cleveland, OH 44115
Edward N. Hanley	Friday, August 11, 1995 - 9:30 A.M.	Hyatt Charlotte 5501 Carnegie Blvd. Charlotte, NC 28202
Christine Incorvaia	Monday, August 14, 1995 - 9:30 A.M.	Silver, Freedman & Taff 1100 New York Ave., NW Suite 700 Washington, DC 20005
Philip Molgren	Monday, August 14, 1995 - 9:20 A.M.	Much, Shelist, Freed, Denenberg & Amend 200 N. LaSalle Street Suite 2100 Chicago, IL 60601

Martis Ann Brachtl, Esquire
Stanley Chesley, Esquire
John J. Cummings, III, Esquire
Calvin Fayard, Jr., Esquire
Wendell Gauthier, Esquire
Will Kemp, Esquire
Arnold Levin, Esquire
Joseph L. Messa, Esquire
Darryl J. Tschirn, Esquire

By_____
Arnold Levin
Liaison Counsel

PLAINTIFFS' LEGAL COMMITTEE

SCHEDULE "A"

I. DEFINITIONS

As used herein, the following terms have the following meanings:

1. The term "document" is used in its broadest possible sense to refer to any document or other tangible matter or thing which may be properly subject to a request under the Freedom of Information Act and your implementing regulations.

2. The term "Cohort Study" refers to the historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar and Sacral Spine Fusions, the results of which were reported to the Orthopedic and Rehabilitation Devices Advisory Committee Panel meeting on July 22, 1994 and in the October, 1994 supplement to *Spine* magazine.

3. The term "relevant premarket notifications" refers to all premarket notifications submitted under Section 510k of the Food, Drug and Cosmetic Act at any time from January 1, 1993 through the present in which the intended use of the device was posterior attachment to the spine by means of screws inserted through the spinal pedicles.

II. DOCUMENTS REQUESTED

1. All documents reflecting, relating or referring, directly or indirectly, to the Cohort Study.

2. All documents reflecting, relating or referring to each and every event involved in planning for the Cohort Study, including any plans or protocols which were abandoned or not otherwise carried out.

3. All documents reflecting, relating or referring to the implementation of any plans for the Cohort Study including transactions undertaken and ultimately not included within the study.

4. All documents reflecting, relating or referring to any results of the Cohort Study including, without limitation, results which were not reported as part of the study.

5. All documents reflecting, relating or referring to any communications among any persons including physicians, organizations of physicians, manufacturers, organizations of manufacturers, the Food and Drug Administration, the National Institute of Health, and any other person, entity or organization with regard to the Cohort Study.

6. All documents reflecting, relating or referring, directly or indirectly, to the payment of money or any item of value to or for the benefit of any person in connection with the Cohort Study.

7. All documents reflecting, relating or referring, directly or indirectly, to clinical data solicited in connection with the Cohort Study.

8. All documents reflecting, relating or referring, directly or indirectly, to the analysis, review, audit, retention and/or destruction of any clinical data solicited or received in connection with the Cohort Study.

9. All documents reflecting, relating or referring to the identity of each and every person who was involved in any aspect of the Cohort Study.

10. All documents reflecting, relating or referring to any audit procedure which was proposed or implemented in connection with the Cohort Study.

11. All documents reflecting, relating or referring to any analysis, summary or meta-analysis of literature with regard to the subject of pedicle screw fixation which was used or proposed to be used in connection with the Cohort Study including analyses used for purposes of selecting study "controls," and meta-analyses and summaries presented or proposed to be presented to the July 22, 1994 Advisory Panel meeting.

12. All documents reflecting, relating or referring to the identity of each physician who submitted data in connection with the Cohort Study.

13. All documents reflecting, relating or referring to any transaction in which any FDA employee or consultant and/or any physician and/or entity who supplied data in connection with the Cohort Study received or had a relative or entity with which he was affiliated receive money, securities, items of value or the promise of money, securities or other items of

value, contingent or otherwise, from any member of the Spinal Implant Manufacturers Group.

14. All documents reflecting, relating or referring, directly or indirectly, to directions, instructions, protocols, procedures, or the like in connection with the Cohort Study.

15. All data derived from the Cohort Study in the form of computer tapes, disks, diskettes, hard drive, or other electronic storage media together with such documents as are necessary for the complete understanding of the manner in which such data have been stored and may be effectively retrieved.

16. All documents reflecting, relating or referring to each and every "control" used in connection with the Cohort Study.

17. All documents reflecting, relating or referring to the payment of money, the conveyance of anything of value or the promise of such payment or conveyance, contingent or otherwise, by any person to or for the benefit of any FDA consultant or any employee of the FDA in connection with the Cohort Study.

18. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant, on the one hand, and any member of the Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Sciolosis Research Society and/or the American Association of Orthopedic Surgeons, on the other had, with respect to the subject of pedicle screw fixation and/or the regulation thereof.

19. Each of the relevant premarket notifications.

20. All documents reflecting, relating or referring to the FDA's consideration of each of the relevant premarket notifications.

21. All documents reflecting, relating or referring to any communications regarding each of the relevant premarket notifications and any agency action thereon.

22. All documents reflecting, relating or referring to each "predicate device" for which substantial equivalence was claimed in each of the relevant premarket notifications.

23. All documents reflecting, relating or referring to any communications between any employee of the FDA and/or any FDA consultant on the one hand, and any member of the

Spinal Implant Manufacturers Group, Advanced Biosearch Associates, North American Spine Society, Sciolosis Research Society and/or the American Association of Orthopedic Surgeons, on the other hand, with respect to each of the relevant premarket notifications.

24. All documents reflecting, relating or referring to the payment of money or the conveyance of any thing of value to or for the benefit of any FDA employee or consultant in connection with any of the relevant premarket notifications and any agency action thereon.

25. All documents which reflect any agency action on each of the relevant premarket notifications.

26. All documents reflecting, relating or referring to the justification for any agency action taken in response to each of the relevant premarket notifications including any agency determination to "clear" a device for use in the human pedicles.

27. All calendars, log books, telephone logs, or other documents reflecting the daily activities and conduct of each deponent to whom this Notice of Deposition and Subpoena Duces Tecum is addressed during the period from January 1, 1993 through the present.

28. All documents reflecting any FDA analysis of data with respect to spinal fixation devices which was generated pursuant to Investigational Device Exemptions granted to Acromed, Inc., Buckman & Company, Sofamor, S.N.C., Stuart, Smith & Nephew Richards, Inc., Zimmer, Advanced Spine Fixation System, Inc., and/or Cross Medical Products.